

RELIANCE® ENDOSCOPE PROCESSING SYSTEM
510(k) Summary

K040049

Non-clinical Tests: Processor Performance, continued	Certification to electromagnetic standards, continued:	
	CISPR 22 (1997) (equivalent to EN 55022:1998)	Limits and Methods of Measurements of Radio Disturbance Characteristics of Information Technology Equipment
Clinical Tests	<p>The Reliance Endoscope Processing System was evaluated in an in-use study in a US hospital. Three flexible endoscopes representing the range of types indicated in the product labeling were used in clinical procedures and processed according to instructions for use. In triplicate evaluations of each endoscope, no organisms were recovered after processing. Bioburden levels on the clinically used endoscopes after manual cleaning and before high level disinfection were determined to be as high as 10^5 CFU/device.</p>	
Conclusion	<p>The above data document that the Reliance Endoscope Processing System meets the FDA requirements of the guidance documents:</p> <ul style="list-style-type: none"> • Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants (2000), and • Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers (1993). <p>Conformity to the requirements of these guidances demonstrates the safety and effectiveness of the Reliance Endoscope Processing System. Based on the results of all testing conducted, this system is as safe and effective as the predicate devices.</p>	

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Device Name	<p>Trade name: The Reliance® Endoscope Processing System</p> <p>Common name: Automated endoscope reprocessing system</p> <p>The System includes the following Classification names:</p> <ul style="list-style-type: none"> • Processor: Medical Washer-Disinfector for High Level Disinfection of Medical Devices • Germicide: Liquid Chemical Germicide • Cleaners: Accessories to the Medical Washer-Disinfector
Legally Marketed Devices to which Substantial Equivalence is Claimed	<p>The Reliance Endoscope Processing System is substantially equivalent to the following legally marketed Class II medical devices:</p> <ul style="list-style-type: none"> • Reliance Processor: Custom Ultrasonic System 83 Plus, based on similar indications for use, designs, and features • Reliance™ DG Dry germicide: STERIS 20™ Sterilant Concentrate, with respect to device design, active ingredient, conditions of use, and chemical monitoring and Sterilox Liquid Chemical HLD System, with respect to indications for use (high level disinfectant) and <i>in situ</i> generation of the active ingredient

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Summary of technological characteristics for comparison to predicate: a) Processor	Property ▼	STERIS Reliance Endoscope Processor		Custom Ultrasonics System 83 Plus	
	Intended Use	Wash and high level disinfect up to two manually pre-cleaned, immersible, reusable, heat-sensitive, semi-critical devices such as GI flexible endoscopes, bronchoscopes and their accessories. High level disinfection is achieved within the 50 - 57°C HLD Phase of the Endoscope Processing Cycle (4-minute generation sequence followed by a 6-minute exposure sequence).		Clean and high level disinfect one or two submersible flexible endoscopes intended used to treat and diagnose disorders of the gastrointestinal and/or pulmonary tracts. High level disinfection contact conditions vary with the germicide used in the processor.	
	Operational Principles	Pressure in control handle boot drives washing/disinfecting/rinse solutions through lumens. Circulation pump sprays exterior surfaces.		Fluid connectors/ attachments flow cleaning/disinfecting/rinse solution through lumens. Immersion system with ultrasonic cavitations during all phases except disinfection.	
		Flow units are required only for endoscope channels that do not open in the endoscope control handle and when mechanical action is required for valve operation		Adaptors are required to flow solutions through lumens.	
	Cycle Description	Phase	Time	Phase	Time
		Optional: Washing 1 (Wash with rinse)	Wash time can be adjusted to be between 5 and 10 minutes	Wash	3 minutes
		Rinse	40 seconds	Rinse	1.5 minutes

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Summary of technological characteristics for comparison to predicate: a) Processor, continued	Property ▼	STERIS Reliance Endoscope Processor		Custom Ultrasonics System 83 Plus	
	Cycle Description, continued	Phase	Time	Phase	Time
		Optional: Washing 2 (Wash with rinse)	Wash time can be adjusted to be between 5 and 10 minutes	Not applicable	
		Rinse	40 seconds		
		Dry Germicide Generation	4 minutes		
		Dry Germicide Exposure	6 minutes	Chemical Immersion	Varies with germicide used
		Rinse 1	40 seconds	Rinse 1	1 minute
		Rinse 2	40 seconds	Rinse 2	1.5 minutes
		Air purge	Air purge time can be adjusted to be between 4 and 30 minutes	Air purge	40 seconds
		Alcohol Flush: Product labeling instructs the user to follow departmental procedures regarding flushing the endoscope channels with alcohol and storage of the endoscope before use.		Alcohol Flush: Product labeling indicates that an alcohol rinse can be performed manually by the user while the device is attached to the processor.	
	Critical Design Features	Intended for use with Reliance DG Dry Germicide only		Intended for use with different types of liquid chemical germicides (aldehydes and most oxidizing germicides)	
		Microprocessor controlled		Microprocessor controlled	
		Internal components constructed of stainless steel and silicone		Internal components constructed of stainless steel	

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Summary of technological characteristics for comparison to predicate: a) Processor, continued	Property ▼	STERIS Reliance Endoscope Processor	Custom Ultrasonics System 83 Plus
	Critical Design Features, continued	Processor provides 0.2 micron filtered water for washing, disinfection and rinsing	Water filtration system external to device (customer supplied)
		Automated injection of washing solution	Manual injection of cleaning solution
		Automated generation and delivery of high level disinfection solution	High level disinfectant selected and added by operator
		Air intake for Air Purge is HEPA filtered	No air cleaning option
	Process Parameters	Can select the following endoscope processing cycles: <ul style="list-style-type: none"> • Disinfect only • Wash and disinfect Processor also provides the following self-decontamination cycles: <ul style="list-style-type: none"> • D-SHORT (must be run every 54 hours) • D-LONG (must be run when D-SHORT has not been run in the past 54 hours) 	Can select the following endoscope processing cycles: <ul style="list-style-type: none"> • Wash only • Wash and disinfect • Disinfect only
		Disinfection time not adjustable	Adjustable disinfection time to accommodate different HLD solutions.
		Washing and air purge times adjustable	Cleaning and air purge times adjustable
		Temperature not adjustable	Temperature is adjustable

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Summary of technological characteristics for comparison to predicate: a) Processor, continued	Property ▼	STERIS Reliance Endoscope Processor	Custom Ultrasonics System 83 Plus
	Process Parameters, continued	Washing solution concentration not adjustable Reliance DG Dry Germicide solution concentration not adjustable	Cleaning solution is added by operator (3 oz. Tergal 800) Liquid chemical germicide solution is adjustable
		Water quality is not adjustable; filtration systems are provided with processor	Water quality external to processor and provided by customer
	Process Monitors	Control Handle Boot pressure alarms if pressure too low to process, or if too high and could potentially damage scopes	Pressure monitor cut off at 5 psi Flow sensor for air/water channel to detect backpressure Air restrictor allowing for visual confirmation of flow (air bubbles) through the air/water channel.
		Detection of a fresh Reliance DG Dry Germicide container in every processing cycle	No on-board monitoring for presence of germicide or germicide components
		Washing solution level monitored; alarm indicates when container does not have sufficient amount to complete cycle	Cleaner solution level not monitored
		Temperature alarms if out of range	No temperature monitoring other than heater thermocouple
		Water filter integrity test	No water filter integrity test
	Maintenance Requirements	D-SHORT decontamination cycle required every 54 hours D-LONG decontamination cycle required if D-SHORT not performed within past 54 hours.	Daily decontamination of internal plumbing using disinfectant solution
		Periodic cleaning of debris screen and spray arms	Daily cleaning with "Comet" or "Ajax" Cleaning when changing disinfectant
		Periodic replacement of water and air filters	Filters provided by customer

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Summary of technological characteristics for comparison to predicate: b) Reliance DG Dry Germicide	Device►	Reliance DG Dry Germicide	STERIS 20	Sterilox Liquid Chemical HLD System
	General Features: The general features of Reliance DG Dry Germicide and the predicate germicides are similar in that they are intended to process pre-cleaned, immersible, reusable medical devices. The germicides are supplied in a ready to use, single use dose.			
	Intended Use:	Dry germicide for use only in the Reliance Endoscope Processor. Provides high level disinfection of up to two manually pre-cleaned, immersible, reusable, heat-sensitive, semi-critical medical devices such as endoscopes and their accessories.	Sterilant for use only in the SYSTEM 1 Processor. Provides sterile processing of manually pre-cleaned immersible, reusable, semi-critical and critical devices.	High level disinfectant for use only with the Sterilox Generator. Provides for high level disinfection of pre-cleaned, immersible, reusable, heat-sensitive, semi-critical medical devices.
	Labeling:	Dry Germicide	Liquid Chemical Sterilant	High Level Disinfectant
	Germicide Exposure Time (min) for intended use (High Level Disinfection or Sterile Processing)	10 (4-minute generation sequence followed by a 6-minute exposure sequence)	12	10
	Use Temperature	50 – 57°C	50 – 56°C	25°C
	Reuse	Single use	Single use	Single use

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Summary of technological characteristics for comparison to predicate: b) Reliance DG Dry Germicide, continued	Device►	Reliance DG Dry Germicide	STERIS 20	Sterilox Liquid Chemical HLD System
	Human Factors	Dispensed ready to use. Container opened automatically by the processor, limiting user exposure to the germicide.	Dispensed ready to use Container opened automatically by the processor, limiting user exposure to the germicide	Dispensed ready to use.
	Physical and Chemical Properties: The physical and chemical properties of Reliance DG Dry Germicide and the predicate germicides are similar in that they are supplied in a single use, ready to use dose in a form that is readily soluble in water and results in a ~ pH neutral solution			
	Container	Single-use, 2 Compartment Container	Single-use, 2 Compartment Container	Single use.
	Composition, Packaged Product	Dry/Dry	Dry/Liquid	Liquid
	Appearance	Translucent liquid	Lime green liquid	Colorless liquid
	Odor	Slightly acidic	Slightly acidic	odorless
	pH	7.0 – 8.5	6 – 8	5 – 7
	Solubility in Water	Complete	Complete	Complete
	Operational Principles – The operational principles of Reliance DG Dry Germicide and the predicate devices are similar in that they result in high level disinfection (or sterile processing for STERIS 20) of the intended devices by direct contact of the germicides with the device surfaces for a specified period of time and temperature, under dynamic conditions. The active ingredient is generated (predicate, Sterilox System) <i>in situ</i> from a ready to use dose of germicide			
	Software controlled parameters	Yes	Yes	Yes
	Form	Water and germicide.	Water and germicide.	Water and germicide.
	Contact	Dynamic liquid contact.	Dynamic liquid contact.	Dynamic or static liquid contact.
	Purpose	Provides high level disinfection when used in the Reliance Endoscope Processor according to labeling.	Provides liquid chemical sterilization when used in the System 1 according to labeling.	Provides High Level Disinfection when used according to labeling.

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Summary of technological characteristics for comparison to predicate: b) Reliance DG Dry Germicide, continued	Device►	Reliance DG Dry Germicide	STERIS 20	Sterilox Liquid Chemical HLD System
	Active Ingredient	Chemical generation of peracetic acid from acetylsalicylic acid and sodium perborate when combined with water in the Reliance Endoscope Processor (<i>in situ</i>).	35% peroxyacetic acid diluted to 0.2 % for use in the SYSTEM 1 Processor.	Electrolytic generation of active (mainly hypochlorous acid) from saline solution in the Sterilox Generator (<i>in situ</i>).
	Mode of Action	It is believed that peracetic acid exerts its germicidal effect by several mechanisms: -oxidizing sulfhydryl and sulfur bonds in proteins and enzymes, particularly in the cell walls ⁸ -hydroxyl radicals produced from PAA are bactericidal ⁹ -PAA damages the viral capsid and viral nucleic acid ^{10,11} .	It is believed that peracetic acid exerts its germicidal effect by several mechanisms: -oxidizing sulfhydryl and sulfur bonds in proteins and enzymes, particularly in the cell walls ¹ -hydroxyl radicals produced from PAA are bactericidal ² -PAA damages the viral capsid and viral nucleic acid ^{3,4}	Attacking the surface and plasma membrane proteins impairs transport of solutes and the salt balance of bacterial cells ¹² .
	Rinses	Automatic, 0.2 micron filtered water.	Automatic, sterile filtered water.	Dependent upon use.
	Microbiology: The microbial efficacy of Reliance DG Dry Germicide and the predicate devices was demonstrated using standard test methodologies. Potency and simulated use tests for Reliance DG Dry Germicide were conducted under worst case operating conditions of the Reliance Endoscope Processor at or below the minimum effective dose of 9000 mg/L PAA min. Standards tests were modified to minimal operating conditions obtained within the Reliance Endoscope Processor. Dacron sutures rather than black waxed silk suture loops were used in sporicidal activity tests as described ¹³ .			

⁸ Block, S. ed., Disinfection, Sterilization, and Preservation. 5th edition, 2001.

⁹ Clapp et al., Free Rad. Res., (1994) 21:147-167.

¹⁰ Maillard et. al., J. Med. Microbiol (1995) 42:415-420.

¹¹ Maillard et. al., J. Appl Bacteriol (1996) 80:540-554.

¹² Pieterston et al., Water SA (1996) 22(1); 43-48.

¹³ McDonnell et al., J. AOAC International (2000) 83:269-275.

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Summary of technological characteristics for comparison to predicate: b) Reliance DG Dry Germicide, continued	Device►	Reliance DG Dry Germicide	STERIS 20	Sterilox Liquid Chemical HLD System
	Sporicidal Activity of Disinfectants AOAC Official Method 966.04	Meets efficacy requirements ¹⁴ . <i>Bacillus subtilis</i> <i>Clostridium sporogenes</i>	Meets efficacy requirements ¹⁴ . <i>Bacillus subtilis</i> <i>Clostridium sporogenes</i>	Meets efficacy requirements ¹⁴ . <i>Bacillus subtilis</i> <i>Clostridium sporogenes</i>
	Confirmatory Sporicidal Activity of Disinfectants AOAC Official Method 966.04	Meets efficacy requirements ¹⁴ . <i>Bacillus subtilis</i> <i>Clostridium sporogenes</i>	Meets efficacy requirements ¹⁴ . <i>Bacillus subtilis</i> <i>Clostridium sporogenes</i>	Meets efficacy requirements ¹⁴ . <i>Bacillus subtilis</i> <i>Clostridium sporogenes</i>
	Fungicidal Activity of Disinfectants AOAC Official Method 955.17	Solution is fungicidal. <i>Trichophyton mentagrophytes</i>	Solution is fungicidal. <i>Trichophyton mentagrophytes</i>	Solution is fungicidal. <i>Trichophyton mentagrophytes</i>
	Use-Dilution Method AOAC, Official Methods 955.14, 955.15, 964.02	Solution is bactericidal. <i>Salmonella choleraesuis</i> <i>Staphylococcus aureus</i> <i>Pseudomonas aeruginosa</i>	Solution is bactericidal. <i>Salmonella choleraesuis</i> <i>Staphylococcus aureus</i> <i>Pseudomonas aeruginosa</i>	Solution is bactericidal. <i>Salmonella choleraesuis</i> <i>Staphylococcus aureus</i> <i>Pseudomonas aeruginosa</i>
	EPA Virucidal Testing (DIS/TSS-7, Nov. 1981)	Process conditions are virucidal. Herpes simplex Type 1 Adenovirus Type 5 Poliovirus Type 1	Solution is virucidal. Herpes simplex Type 2 Poliovirus Type 1 Influenza A	Solution is virucidal Herpes simplex Type 1 Poliovirus Type 2 Human immunodeficiency virus Type I
	Tuberculocidal Activity of Disinfectants AOAC Official Method 965.12	Solution is tuberculocidal. <i>Mycobacterium bovis</i>	Solution is tuberculocidal. <i>Mycobacterium bovis</i>	Solution is tuberculocidal. <i>Mycobacterium bovis</i>
	Tuberculocidal Activity Ascenzi Quantitative Suspension Test	Solution is tuberculocidal <i>Mycobacterium terrae</i>	Not performed	Unknown

¹⁴ McDonnell et al., J. AOAC International (2000) 83:269-275.

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Summary of technological characteristics for comparison to predicate: b) Reliance DG Dry Germicide, continued	Device▶	Reliance DG Dry Germicide		STERIS 20	Sterilox Liquid Chemical HLD System
	Simulated-Use Test	Meets efficacy requirement <i>Mycobacterium terrae</i>		Meets efficacy requirement <i>Bacillus subtilis</i> spores <i>Geobacillus stearothermophilus</i> spores	Meets efficacy requirement <i>Mycobacterium terrae</i>
	Clinical In-Use	No surviving microorganisms on any of the endoscopes or accessories tested		Not required at time of submission.	No surviving microorganisms on the endoscopes tested.
	Toxicology: Toxicology of the Reliance DG Dry Germicide use dilution and its predicate devices were characterized with acute toxicity tests.				
	Rat Acute Oral Toxicity – Use Dilution	LD ₅₀ = >5000 mg/kg		LD ₅₀ = >10,000 mg/kg	LD ₅₀ = >5000 mg/kg
	Rabbit Eye Irritation	Minimally irritating		Minimally irritating	Non-irritating
	Rabbit Skin Irritation	Non-irritating		Non-irritating	Non-irritating
	Cytotoxicity	Dilution	Cytotoxicity Score	Not tested	Not tested
		1:1 to 1:2	3 -moderate		
		1:4 to 1:16	2 – mild		
		1:20	1 – slight		
		1:40	0 – nontoxic		
Residues: Residues of Reliance DG Dry Germicide and its predicate devices have been shown to be effectively reduced to safe levels through chemical analysis of medical device extracts.					
Residue Reduction	Automatic within the Reliance Endoscope Processor, 2 x 15 L - 0.2 µ filtered water rinses effectively reduces germicide residues to safe levels.		Automatic within SYSTEM 1 Processor, 4 x 10 L sterile filtered water rinses effectively reduce germicide residues to safe levels.	Effectively removed from devices by the rinses following disinfection.	
Reusable Device Compatibility: The medical device compatibility of Reliance DG Dry Germicide and its predicate devices was established through testing with finished devices or device materials of construction.					

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	Device ►	Reliance DG	STERIS 20	Sterilox Liquid Chemical HLD System
Summary of technological characteristics for comparison to predicate: b) Reliance DG Dry Germicide, continued	Device Material Compatibility	Compatible with intended flexible endoscopes and accessories established through testing finished medical devices. No device functional changes. Some materials show cosmetic changes such as fading of external markings but all remained legible, and bleaching of black anodized aluminum without harm to the base material.	Compatible with medical devices and materials of their construction. No device functional changes. Some materials show cosmetic changes such as fading of external markings but all remained legible, and bleaching of black anodized aluminum without harm to the base material.	Does not produce any corrosion or other visible damage in the majority of endoscope components. Color changes and the "tack" of the coating of the outer endoscope sheaths were noted on some endoscopes. Corrosion was noted on anodized aluminum.
	Chemical Indicator: Chemical monitoring of Reliance DG Dry Germicide and its predicate device (STERIS 20) is accomplished through a chemical reaction on an indicator pad in the presence of active ingredient.			
	Chemical Monitoring	Reliance PI, Process Indicator (separate submission). Chemical reaction on indicator pad to produce color change.	STERIS PROCESS Indicator Chemical Monitor (K921559). Chemical reaction on indicator pad to produce color change.	Pre-programmed colorimetric for direct-reading of chlorine concentration.

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<p>Device Description</p>	<p>The Reliance Endoscope Processing System is a combination of products that are used to wash and high level disinfect flexible endoscopes and their accessories.</p> <ul style="list-style-type: none"> • The Reliance Endoscope Processor is an electromechanical washer/high level disinfectant with a microprocessor-based controller that provides for automated endoscope processing cycles and processor self-decontamination cycles. • The processor utilizes a proprietary, single use, dry, germicide package (Reliance DG Dry Germicide) that generates the active ingredient, peracetic acid, upon automatic dilution in water by the processor. • In the optional washing phase of the endoscope processing cycle, washing is provided through the automated delivery of Klenzyme Enzymatic Presoak and Cleaner, a currently marketed product for manual cleaning of medical devices. • CIP 200 Acid-Based Process and Research Cleaner, a currently marketed general cleaning agent, is used in one of the two self-decontamination cycles provided by the processor. <p>The Reliance Endoscope Processing System provides for cycles with the following features:</p> <ul style="list-style-type: none"> • Endoscope Processing Cycle <ul style="list-style-type: none"> ⇒ The first part of this cycle is an optional programmable washing phase. This phase consists of a wash that uses Klenzyme, followed by a rinse. The washing phase can be programmed on or off. In the "on" mode, the user can choose either one or two washing phases per processing cycle, and the wash time can be adjusted to be between 5 and 10 minutes. <i>The Reliance washing phase does not replace manual pre-cleaning by the user.</i> ⇒ The second part is a high level disinfection phase that is non-optional and the parameters cannot be changed by the user. In this phase, the proprietary Reliance DG Dry Germicide components, provided in a single use container, are dissolved with water at ~50°C and circulated throughout the processor and through device lumens for a 6 minute exposure time.
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<p>Device Description, continued</p>	<ul style="list-style-type: none"> ⇒ Following high level disinfection, the Reliance Endoscope Processor removes the high level disinfection solution through a rinse phase which is non-optional and the parameters cannot be changed by the user. The processor filters the rinse water (as well as all of the water used throughout the cycle) through a 0.2 micron bacterial-retentive filter. It also incorporates an automatic internal integrity check of this filter at the end of each processing cycle. If the integrity check fails, an alarm alerts the user, and the processor does not complete the cycle. ⇒ The last step in the processing cycle is an air purge phase using HEPA-filtered air. The air purge helps to remove excess rinse water from the processed devices. The final air purge is preset to run for 4 minutes; additional air purge time may be selected by the operator. ⇒ The processor will print a detailed cycle summary at the end of each cycle that includes information such as processor number, cycle date, start and stop times, as well as phase parameters. With an optional bar code reader, the printouts can also include identification numbers for the operator, patient, device, doctor and procedure. <ul style="list-style-type: none"> • Decontamination Cycles The processor also features two decontamination cycles that are to be used without endoscopes in the processor: <ul style="list-style-type: none"> ⇒ The first, called D-SHORT, consists of hot water circulating through the processor for 10 minutes, followed by a 10-minute hot air purge. This cycle is to be run every 54 hours. D-SHORT is intended to prevent biofilm from forming. ⇒ The second, called D-LONG, consists of a cycle in which CIP 200 Acid-Based Process and Research Cleaner is added to hot water. The cleaning solution is then circulated through the processor for 20 minutes; this is followed by three rinses to remove the solution from the processor and a 10-minute hot air purge. D-LONG is to be used on those occasions when the D-SHORT cycle has not been run within the past 54 hours.
<p>Intended Use</p>	<p>The Reliance Endoscope Processing System is intended for washing and high level disinfection of up to two manually pre-cleaned, immersible, reusable, heat-sensitive, semi-critical devices such as GI flexible endoscopes, bronchoscopes and their accessories. High level disinfection is achieved within the 50 - 57°C HLD Phase of the Endoscope Processing Cycle (4-minute generation sequence followed by a 6-minute exposure sequence).</p>

RELIANCE® ENDOSCOPE PROCESSING SYSTEM **510(k) Summary**

<p>Non-clinical Tests: Germicide Efficacy</p>	<p>The Reliance Endoscope Processing System was developed and validated in accord with two primary FDA Guidance documents:</p> <ul style="list-style-type: none"> • Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectant (2000), and • Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers (1993). <p>A summary of this testing follows:</p> <ul style="list-style-type: none"> • Reliance DG Dry Germicide Efficacy: Reliance DG Dry Germicide was tested and shown to generate an effective high level disinfection solution using the standard array of microbiological tests for germicidal efficacy. The testing was performed at conditions of use that were worst case with respect to germicide concentration, contact time, circulation, water hardness, temperature and artificial soiling. <ul style="list-style-type: none"> ⇒ Sporicidal: Reliance DG Dry Germicide was proven to be sporicidal as defined by AOAC Sporocidal Activity Test with an <i>in situ</i> exposure time of 6 minutes. Confirmatory testing was completed successfully and supplemental confirmatory testing was completed in the Reliance Endoscope Processor. Potency was subsequently confirmed in the processor using Reliance DG Dry Germicide containers that were aged beyond the end of its shelf life. ⇒ Tuberculocidal: Reliance DG Dry Germicide was proven to be tuberculocidal as defined by the AOAC Tuberculocidal Activity Test with an exposure time of 6 minutes. Potency was subsequently confirmed using Reliance DG Dry Germicide aged beyond the end of its shelf life. ⇒ Virucidal: The Reliance Process was proven to reduce the viable population of poliovirus Type 1, adenovirus Type 5, and herpes simplex virus Type 1 by $> 4 \log_{10}$. ⇒ Bactericidal: Reliance DG Dry Germicide was proven to be bactericidal as defined by the AOAC Bactericidal Activity Test with an exposure time of 6 minutes at worst case conditions, whether performed <i>in situ</i> or <i>in vitro</i>. ⇒ Fungicidal: Reliance DG Dry Germicide was proven to be fungicidal as defined by the AOAC Fungicidal Activity Test with an exposure time of 6 minutes, whether performed <i>in situ</i> or <i>in vitro</i>. • Simulated-Use: Reliance DG Dry Germicide, at the minimum recommended dose, reproducibly achieved greater than a $6 \log_{10}$ reduction of <i>Mycobacterium terrae</i> in triplicate trials within the Reliance Endoscope Processor for selected clinically relevant flexible endoscopes and their accessories. The test articles represented the range of most challenging devices, accessories, and processing situations.
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<p>Non-clinical tests: Germicide Biocompatibility, Material Compatibility and Stability</p>	<ul style="list-style-type: none"> • Biocompatibility: The Reliance chemical formulations, as supplied in packaging as well as in use dilutions, can be safely handled and used by customers. Residues that may remain on medical endoscopes and accessories are below established residue limits and do not pose a risk to patients. Safety statements in product labeling are appropriate to the potential risk. <ul style="list-style-type: none"> ⇒ Reliance DG Dry Germicide, its components, reaction products, and residuals remaining on medical devices were evaluated for biocompatibility and possible risks to users. Testing included acute oral and ocular toxicity tests, dermal irritation studies, <i>in vitro</i> bacterial mutation genotoxicity studies, sensitization tests, and <i>in vitro</i> cytotoxicity evaluations; literature reviews of raw material toxicity data were also performed. Certain components in the single-use container, which under normal use conditions never contact the user, have the potential for irritation or skin sensitization; therefore appropriate warnings and instructions are displayed on labeling for the unusual event of a spill or container breakage. ⇒ Use dilution reaches non-cytotoxic levels with minimal dilution. ⇒ Biocompatibility testing of extracts from processed medical devices demonstrated that no toxic residuals remain on devices under worst case circumstances. The test data indicate that the worst case residue levels for the components of maximum potential risk are far below the allowable limits. Furthermore, the processor final rinse water was found to be non-cytotoxic. • Reliance Endoscope Processing System Material Compatibility: The Reliance System was evaluated for its effect on intact medical devices, including flexible endoscopes and/or common materials of device construction. After 300 processing cycles, no deleterious effects were observed other than minor cosmetic changes similar to those seen with the predicate device (STERIS 20). No functional changes in flexible endoscopes were observed. • Reliance DG Dry Germicide Stability: Reliance DG Dry Germicide was tested and found stable for 18 months in the unopened moisture-resistant foil pouch at the stated conditions for storage. Once opened, the containers within each pouch are to be used within 2 weeks, or by the expiration date on the container, whichever comes first.
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<p>Non-clinical Tests: Processor Performance</p>	<ul style="list-style-type: none"> • Reliance Endoscope Processor Performance The critical process parameters for the processor (water temperature and volume, fresh Reliance DG Dry Germicide container detection, boot pressure, delivery of washing solutions and high level disinfection solution and water filter integrity testing) were each evaluated in replicate under worst case conditions and found to be within required specifications. Each processor phase or cycle was separately evaluated and documented to be effective under worst case conditions: <ul style="list-style-type: none"> ⇒ Validation of the washing phase of the Endoscope Processing Cycle documented that after the shortest possible washing phase, devices pre-soiled with a combination of eggs, blood, mucin and serum in saline: 1) were visually clean, and 2) achieved greatly reduced yield of extractable protein per cm² device area (assayed to be reduced from ≥ 173 to ≤ 5 µg/cm²). ⇒ Validation of the high level disinfection phase of the Endoscope Processing Cycle was performed through a simulated-use study in challenging clinically relevant endoscopes as described above, as well as in the in-use study described below. ⇒ The rinse phase of the endoscope processing cycle was shown to be effective. Evaluations of extracts of devices exposed to worst case conditions in the Endoscope Processing Cycle documented that levels of residuals remaining on devices were far below allowable limits and were not cytotoxic. ⇒ The air purge phase was validated to confirm the ability to remove rinse water from processed medical devices. ⇒ The filter integrity test system of the processor was documented to reliably detect filter failure. ⇒ The two self-decontamination cycles were shown to be effective as follows: D-LONG cycle – can disinfect the Reliance Endoscope Processor after a high level challenge with <i>P. aeruginosa</i> followed by a 5 day inactive period; D-SHORT cycle – can kill bacteria that have potential to form biofilm.
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RELIANCE® ENDOSCOPE PROCESSING SYSTEM
510(k) Summary

Non-clinical Tests: Processor Performance, continued	<ul style="list-style-type: none"> In addition, the Reliance Endoscope Processor has been certified to the following electrical standards: 		
	UL 3101-1 First Edition (1993)		The Standard for Safety of Laboratory Use Electrical Equipment
	CAN/CSA C22.2 No. 1010.1-92 (1992)		Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use
	CENELEC EN 61010-1: 1993 + A2: 1995		Safety Requirements for Electrical Equipment for Measurements, Control and Laboratory Use Part 1: General Requirements (IEC 61010-1:1990 + A1: 1992, modified +A2:1995)
	IEC 61010-2-045 (2000)		Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 2-045: Particular Requirements for Washer Disinfectors Used in Medical, Pharmaceutical, Veterinary and Laboratory Fields
	CENELEC EN 61326 (1998)		Electrical Equipment for Measurement Control and Laboratory Use, EMC Requirements Part: General Requirements Including Amendments A1:1998; IEC 61326:1997 + A1: 1998
	EN 55011 (1998)		Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment – Radio Disturbance Characteristics – Limits and Methods of Measurement
	EN 50082 (1997)		Electromagnetic Compatibility – Generic Immunity Standard – Part 1 Residential, Commercial and Light Industry
	EN 61000		Testing and Measurement Techniques
		Part 4-2 (1999)	Electrostatic Discharge Immunity Test, Level 3
		Part 4-3 (1996)	Radiated, Radio-Frequency, Electromagnetic Field Immunity Test (<i>in situ</i>)
		Part 4-4 (1995)	Electrical Fast Transient/Burst Immunity Test, Level 3
		Part 4-5 (1995)	Surge Immunity Test, Level 3
		Part 4-6 (1996)	Conducted RF Immunity Test, Level 2

RELIANCE® ENDOSCOPE PROCESSING SYSTEM
510(k) Summary

Non-clinical Tests: Processor Performance, continued	Certification to electromagnetic standards, continued:	
	CISPR 22 (1997) (equivalent to EN 55022:1998)	Limits and Methods of Measurements of Radio Disturbance Characteristics of Information Technology Equipment
Clinical Tests	<p>The Reliance Endoscope Processing System was evaluated in an in-use study in a US hospital. Three flexible endoscopes representing the range of types indicated in the product labeling were used in clinical procedures and processed according to instructions for use. In triplicate evaluations of each endoscope, no organisms were recovered after processing. Bioburden levels on the clinically used endoscopes after manual cleaning and before high level disinfection were determined to be as high as 10^5 CFU/device.</p>	



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

STERIS Corporation
c/o Mark A. Heller
Wilmer Cutler Pickering Hale and Dorr, LLP
The Willard Office Building
1455 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

JUL 21 2006

Re: k040049

Trade/Device Name: Reliance® Endoscope Processing System
Regulation Number: 21 CFR 876.1500
Regulation Name: For Endoscopes Cleaning Germicide Accessories
Regulatory Class: Class II
Product Code: NZA
Dated: October 31, 2005
Received: October 31, 2005

Dear Mr. Heller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

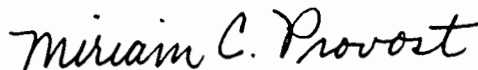
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276- 0115. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,

Handwritten signature of Miriam C. Provost in black ink.

for

Donna-Bea Tillman, Ph.D., M.P.A.

Director

Office of Device Evaluation

Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K040049

Device Name: Reliance® Endoscope Processing System

Indications for Use:

The Reliance Endoscope Processing System is intended for washing and high level disinfection of up to two manually pre-cleaned, immersible, reusable, heat-sensitive, semi-critical devices such as GI flexible endoscopes, bronchoscopes and their accessories. High level disinfection is achieved within the 50 -57°C HLD Phase of the Endoscope Processing Cycle (4 minute generation sequence followed by a 6 minute exposure sequence).

Prescription Use _____ AND/OR Over-The-Counter Use ____X____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost for DBT

(Sign-Off)
Director of Anesthesiology, General Hospital,
Regulatory Control, Dental Devices

Device Number: K040049

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(Posted November 13, 2003)